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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,073

08/26/2003

Steven E. Hobbs

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05/16/2007

NANOSTREAM, INC.

C/O INTELLECTUAL PROPERTY/TECHNOLOGY LAW

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RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1743

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/649,073

Applicant(s)

HOBBS ET AL.

Examiner

Natalia Levkovich

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1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13/01/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-31 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13 and 15--21 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1,3-13 and 15-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks dated 03/01/2007 have been acknowledged by the Examiner.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-13, 15-21 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 11 and 26 recite the 'surface of a non-elastomeric material'. Upon further reviewing the original specification, the Examiner found no support for this limitation. The specification supports 'plastically deformable' outer layers, or describes

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elastomeric outer layers in prior art. However, Examiner failed to find a recitation of the non-elastomeric outer layer in the instant written description.

5. Claims 1, 3-13, 15-21 and 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 4, 'substantially enclosed' channel, is unclear. Also see claims 11 and 26.

Claim Rejections - 35 USC § 103

6. Claims 1, 3-11, 15-21 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staats (US 7060227).

Referring to claims 1, 11, and 26, Staats discloses a microfluidic assembly comprising, as shown in Figure 4, microfluidic substrate 40 ['microfluidic device' – Ex.] with a microchannel / aperture (not indexed) parallel to the outer surface of the substrate; substrate 70 ['retractable element external to the fluidic structure of substrate 40' – Ex.] with a second aperture and protrusions ['continuous raised features' – Ex.] 60, the second aperture and the protrusions forming a mating surface. "Mechanical pressure such as one exerted by a clamp ['linear actuator', or compression element for compressing the microfluidic device and the 'external retractable element' together' – Ex.] over the alignment features may be sufficient to secure the two substrates together to form a liquid-tight seal" (Col.4, lines 3-5). Staats also teaches a wide variety of the materials forming the microfluidic features: "the materials... may be organic, inorganic,

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or a blend of organic and inorganic materials”, which would include non-elastomeric materials (Col.11, lines 10-15).

Although Staats discloses multi-layered micro-fluidic devices, the reference does not specifically teach coated surfaces / ‘outer layers’. However, such layers are routinely used in the art, especially in planar technologies. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed outer layers / coatings in the modified apparatus of Staats, in order to obtain surfaces with desired physical / chemical characteristics (including ‘non-elastomeric’ properties).

With respect to claims 3 and 15, Staats teaches in column 13, lines 10-13, that the disclosed microfluidic structures can perform “operations such as liquid chromatography, electrophoresis and the like”.

Referring to claims 4, 6 and 17, Staats discloses some polymeric substrate materials, such as PMMA, as being usable in the art “because of its optical clarity in the visible wavelengths making it suitable for laser induced fluorescence (LIF) detection” (Col.2, line 35).

Regarding claim 5, Staats teaches adhesive bonding in column 3, lines 60-65.

In reference to claims 7, 16, 18 and 30, Staats teaches polyethylene and polypropylene in column 9, lines 40-45.

With respect to claims 8 and 19, Staats does not teach the mating surface being made of a material having hardness greater than the hardness of the corresponding coating / outer layer. However, the use of harder structures for making impressions / ‘plastically deforming’ in softer materials is notoriously well known. It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to have employed protrusions of higher hardness (relative to the one of a corresponding surface to be mated with), in the modified apparatus of Staats, in order to provide a tighter sealing for the device.

Regarding claims 9 and 20, Staats teaches "plunger or piston-like structures" in column 7, lines 35-40.

Regarding claims 10 and 21, Staats does not teach sensors, however, microfluidic devices comprising position or compression sensors are commonly employed in the art. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed such sensors in the modified apparatus of Staats, in order to control the quality of sealing.

7. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staats in view of Paul et al. (US 20040011648).

Although Staats is concerned with providing reliable sealing and discloses the pressure-driven fluid flow in micro-fluidic devices to be very well known, the reference does not teach the apparatus to be employed at elevated pressures and, therefore, to include sealing means capable to withstand such pressures (in particular, up to 500 psi). Paul discloses microfluidic flow devices which "include: a wide variety of different micro-components" and can incorporate "a high integrity seal that can withstand pressures in excess of 500 psi required for chromatographic separation and/or chemical processing" – (see [0061]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the sealing means in the modified

apparatus of Staats such that the seal would withstand the high pressure, in order to improve the sealing and to enhance the scope of applicability of the device.

Response to Arguments

8. Applicant's arguments dated 03/01/2007 have been fully considered but they are not persuasive, or moot in view of the new grounds of rejection.

Applicant argues that 'nothing in Staats teaches or remotely suggests any retractable element that is external to a channel-defining microfluidic device, let alone a retractable element having a continuous raised feature surrounding an aperture, with the continuous raised feature being compressible into an outer surface or layer of the microfluidic device to permit fluid transfer between the retractable element and microfluidic device when the continuous raised feature is depressed into such outer surface or layer'. Examiner disagrees. Figure 4 does show the 'retractable element' 70 that is 'external to a channel-defining' microfluidic device 40. The 'compressible raised feature' 60 surrounding the 'second aperture' appears to be continuous, and, if not, it would have been clearly within the ordinary skill of an artisan to have modified the apparatus of Staats such as to have a continuous protrusion around the aperture, in order to provide additional sealing.

Applicant argues that 'nothing in Paul teaches or remotely suggests any retractable element that is external to a channel-defining microfluidic device and has a continuous raised feature surrounding an aperture, with the continuous raised feature being compressible into an outer surface or layer of the microfluidic device to permit

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fluid transfer between the retractable element and microfluidic device when the continuous raised feature is depressed into such outer surface or layer. Examiner agrees with this statement and notes that Paul was cited to support the idea of the apparatus configured to be employed at elevated pressures (see the discussion above).

Applicant argues that 'nothing in Staats teaches or remotely suggests than any structure external to the microfluidic device should be depressed against the microfluidic device to plastically deform an outer surface or layer of the device to form a fluidic interface', that 'nothing in Staats teaches any structure external to a microfluidic device that defines an aperture surrounded by a raised feature for depression into an external portion of a microfluidic device', because 'Staats teaches that fluidic interfaces with assembled (i.e., closed-channel-defining) microfluidic devices should be made by way of integral raised capillaries that protrude outward from the microfluidic device'. Examiner disagrees. Staats does teach an external retractable element with raised feature capable of being pressed (for example, by a clamp) to a micro-fluidic device, to form a 'substantially enclosed channel (see the discussion above).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
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